



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents  
United States Patent and Trademark Office  
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Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

OCT 18 2010

David B. Quick  
ICE MILLER LLP  
One American Square  
Suite 2900  
Indianapolis, IN 46282-0200

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,919,140

Dear Mr. Quick :

An order granting interim extension under 35 U.S.C. § 156(d)(5) is enclosed extending the term of U.S. Patent No. 4,919,140 for a period of 1 year. A copy of the Federal Register notice published in accordance with 35 U.S.C. 156(d)(5)(B) on October 13, 2009 at 75 Fed. Reg. 62767 is enclosed herewith. While a courtesy copy of this letter and the interim extension is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to patent expiration dates.

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at [mary.till@uspto.gov](mailto:mary.till@uspto.gov).

Mary C. Till

Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc:     Office of Regulatory Policy  
         Food and Drug Administration  
         10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
         Silver Spring, MD 20993-0002

RE: Andara™ OFSTM System  
FDA Docket No.:

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Purdue Research Foundation  
Request for Patent Term Extension  
U.S. Patent No. 4,919,140

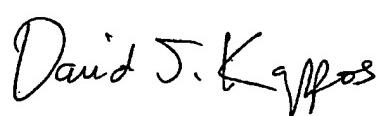
: ORDER GRANTING  
: INTERIM EXTENSION

On September 13, 2010, the patent owner, Purdue Research Foundation, timely filed a third application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,919,140. The patent claims the medical device known as Andara™ OFSTM System and a method of using the Andara™ OFSTM System. The application indicates that a Humanitarian Device Exemption, HDE 070002, for the medical device Andara™ OFSTM System has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for an additional one year as required by 35 U.S.C. § 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (October 14, 2010), interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

A third interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,919,140 is granted for a period of one year from the extended expiration date of the patent, i.e., until October 14, 2011.

October 8, 2010



Date

David J. Kappos  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office

Dated: October 7, 2010.

**Robert W. Bahr,**

*Acting Associate Commissioner for Patent Examination Policy, United States Patent and Trademark Office.*

[FR Doc. 2010-25768 Filed 10-12-10; 8:45 am]

BILLING CODE 3510-16-P

#### DEPARTMENT OF COMMERCE

**United States Patent and Trademark Office**

[Docket No. PTO-P-PTO-P-2010-0081]

#### Grant of Interim Extension of the Term of U.S. Patent No. 4,919,140; Andara™ OFS™ System

**AGENCY:** United States Patent and Trademark Office.

**ACTION:** Notice of interim patent term extension.

**SUMMARY:** The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. 156(d)(5) for a third one-year interim extension of the term of U.S. Patent No. 4,919,140.

**FOR FURTHER INFORMATION CONTACT:** Mary C. Till by telephone at (571) 272-7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571) 273-7755, or by e-mail to [Mary.Till@uspto.gov](mailto:Mary.Till@uspto.gov).

**SUPPLEMENTARY INFORMATION:** Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for

interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On September 13, 2010, the patent owner, Purdue Research Foundation, timely filed an application under 35 U.S.C. 156(d)(5) for a third interim extension of the term of U.S. Patent No. 4,919,140. The patent claims the medical device Andara™ OFS™ System and a method of using the Andara™ OFS™ System. The application indicates that a Humanitarian Device Exemption, HDE 070002, for the medical device Andara™ OFS™ System has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for an additional one year as required by 35 U.S.C. 156(d)(5)(B). Because it is apparent that the regulatory review period will continue beyond the extended expiration date of the patent (October 14, 2010), interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

A third interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 4,919,140 is granted for a period of one year from the extended expiration date of the patent, *i.e.*, until October 14, 2011.

Dated: October 7, 2010.

**Robert W. Bahr,**

*Acting Associate Commissioner for Patent Examination Policy, United States Patent and Trademark Office.*

[FR Doc. 2010-25767 Filed 10-12-10; 8:45 am]

BILLING CODE 3510-16-P

#### DEPARTMENT OF DEFENSE

##### Office of the Secretary

[Transmittal Nos. 10-53, 10-54, 10-55, 10-59, 10-60, 10-61, and 10-63]

##### 36(b)(1) Arms Sales Notifications

**AGENCY:** Defense Security Cooperation Agency, DoD.

**ACTION:** Notice.

**SUMMARY:** The Department of Defense is publishing the unclassified text of seven section 36(b)(1) arms sales notifications to fulfill the requirements of section 155 of Public Law 104-164, dated 21 July 1996.

**FOR FURTHER INFORMATION CONTACT:** Ms. B. English, DSCA/DBO/CFM, (703) 601-3740.

**SUPPLEMENTARY INFORMATION:** The following are copies of letters to the Speaker of the House of Representatives, Transmittals 10-53, 10-54, 10-55, 10-59, 10-60, 10-61, and 10-63 with associated attachments.

Dated: October 6, 2010.

**Mitchell S. Bryman,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

##### Transmittal No. 10-53

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 10-53 with attached transmittal and policy justification.

BILLING CODE 5001-06-P